

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/39		A1	(11) International Publication Number: WO 99/66850 (43) International Publication Date: 29 December 1999 (29.12.99)
(21) International Application Number: PCT/DK98/00276 (22) International Filing Date: 22 June 1998 (22.06.98)		(81) Designated States: JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(71) Applicant (<i>for all designated States except US</i>): LINA MEDICAL APS [DK/DK]; Formervangen 5, DK-2600 Glostrup (DK). (72) Inventor; and (75) Inventor/Applicant (<i>for US only</i>): KORNERUP, Niels [DK/DK]; Gl. Vallerødvej 31 A, DK-2960 Rungsted (DK). (74) Agent: OSTENFELD PATENTBUREAU A/S; Bredgade 41, P.O. Box 1183, DK-1011 Copenhagen K (DK).		Published <i>With international search report.</i>	
(54) Title: AN ELECTROSURGICAL DEVICE FOR COAGULATING AND FOR MAKING INCISIONS, A METHOD OF SEVERING BLOOD VESSELS AND A METHOD OF COAGULATING AND FOR MAKING INCISIONS IN OR SEVERING TISSUE			
(57) Abstract <p>An electrosurgical device for coagulating and for making incisions in or severing tissue such as blood vessels, the device comprising forceps jaws (6, 7) for immobilising a tissue portion to be coagulated and incised, the forceps jaws (6, 7) being connected to means for applying an electrical tension between said forceps jaws for coagulating the tissue portion, the device further comprising a member (22) for being displaced between said forceps jaws (6, 7) to incise a tissue portion held between the forceps jaws and coagulated thereby, the member (22) being connected to means for applying an electrical voltage to said member for performing an incision in said tissue by means of said electrical voltage applied to said member (22), the member (22) preferably being blunt such that the incision substantially exclusively is achieved by means of the voltage applied to the member.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

An electrosurgical device for coagulating and for making incisions, a method of severing blood vessels and a method of coagulating and for making incisions in or severing tissue.

5

The present invention relates to an electrosurgical device for coagulating and for making incisions in or severing tissue such as for instance blood vessels, said device comprising at least one immobilizing means for immobilizing a tissue portion to be coagulated and incised and first 10 electrical means for applying a first electric power to the tissue portion immobilized by the immobilizing means for coagulating at least part of said tissue portion.

An electrosurgical device of this type is disclosed in US patent No. 15 5,445,638 to Rydell et al. In this known device two moveable forceps jaws are provided for clamping the tissue portion therebetween, the forceps jaws being provided with electrical means to provide electric power for coagulating the tissue portion clamped therebetween. A cutting instrument with one or more cutting edges is provided for being moved between the 20 forceps jaws for mechanically cutting the tissue portion after coagulation thereof has taken place.

When tissue such as for instance a blood vessel has been coagulated, the 25 tissue often becomes relatively tough requiring a relatively large force to be exerted on the cutting instrument to perform the required incision. Furthermore each incision dulls the cutting edge thereby requiring even larger force for each incision. In many cases, the cutting edge has been dulled so much after one or two incisions that the device must be replaced if, as is often the case, several incision are to be performed during the 30 same operation. As the device normally is intended to be discarded after use, this is expensive, and furthermore, it is not desirable to have to remove and introduce such devices during such surgery.

Additionally, because of the toughness of the tissue and the manual 35 application of the cutting force, the manipulation of the device is less smooth and easy than desirable, and the cutting operation may give rise to a snap-like reaction which is undesirable in this type of surgery.

A main object of the invention is thus to provide an electrosurgical device of the type in reference by means of which multiple incisions may be performed with the same device and without the disadvantages of the
5 known device described above.

According to the invention, this object is achieved by providing the device with at least one electric power application means for applying a second electric power to at least part of said tissue portion for making incisions in
10 said tissue portion.

Hereby, the second electric power applied gives rise to a thermal influence on the tissue portion whereby the incision is performed by the effects of the thermal influence which is not subject to alteration from incision to
15 incision and therefore gives uniform handling characteristics as well as a smooth and easy operation because the toughness of the tissue has very reduced or no effect on the force to be exerted for performing the incision. By thermal influence is meant herein the diverse effects of electric power applied to tissue and which are well known to those skilled in the art.

20 Although, for some uses, it may be advantageous to combine a mechanical cutting effect with the thermal cutting effect for instance by providing the electric power application means according to the invention with a mechanical cutting edge, in the currently preferred device according to the
25 invention, the electric power application means are configured such, for instance being blunt, that the incision or severing is substantially exclusively achieved by means of said second electric power.

30 Hereby it is achieved that the cutting characteristics of the device are not influenced at all by any dulling of a cutting edge. Furthermore, this feature is advantageous in that the risk of cutting through tissue that has not been adequately coagulated for eliminating bleeding is greatly reduced or eliminated because the thermal effect of the second electric power applied by the electric power application means will tend to coagulate any tissue
35 that has not been sufficiently coagulated by the application of the first electric power.

In the known device described above, the severing of a blood vessel, for instance, where the coagulation has not been performed correctly or insufficiently will give rise to bleeding when the blood vessel is severed by the cutting edge while the device according to the invention will tend to 5 coagulate any insufficiently coagulated tissue or blood while performing the severing operation. This affords a device with a greatly increased safety margin whereby complications during surgery are reduced both in number and severity.

10

According to the invention and depending on the characteristics of the surgery to be performed, the first and/or the second electrical power may be constituted by an electric current signal, an electric voltage signal or a combination thereof, and the signal may be a DC or AC signal such as a 15 LF, an HF or an RF signal for instance a VHF, a UHF or a microwave signal.

20

In the currently preferred embodiment of the device according to the invention, the first and second electric powers are obtained by means of substantially identical electric current or voltage signals. Hereby a 25 common, relatively inexpensive signal generating means may be employed for generating the required signals. However, for some applications it may be advantageous that the respective electric current or voltage signals be different so as to obtain, for instance, a relatively higher incision power than coagulating power.

30

Although many different types of grasping means, pinning means and the like may be utilized as tissue immobilizing means, in the currently preferred embodiment of the device according to the invention, the immobilizing means comprise first and second moveable forceps jaws and moving means for opening and closing the first and second jaws relative to one another for holding and/or clamping the tissue portion therebetween.

35

When severing blood vessels it is important that the vessel be compressed to the correct degree to achieve the desired coagulation. Therefore, in the currently preferred embodiment of the device according to the invention, the moving means comprise adjustable spring loading means for applying a

specific or an adjustable spring load for closing the first and second jaws relative to one another, and the spring load may be manually adjustable depending on the characteristics of the tissue portion to be held between said jaws. Hereby, the clamping effect may be adjusted according to the 5 diameter, type and degree of calcification of the blood vessel to be severed. The surgeon may thus adjust the spring load and thereby the clamping effect prior to performing the severing of the blood vessel and thus avoid the inconvenience and complication of the known device described above where the surgeon must maintain the pressure manually 10 during almost the whole severing operation.

In the currently preferred embodiment of the device according to the invention, the device furthermore comprises electrical switching means for applying the first and second electric powers independently of one another 15 and preferably sequentially.

The currently preferred embodiment of the device according to the invention comprises:
an elongated tubular member having a proximal and a distal end and a 20 lumen extending therethrough,
first and second moveable forceps jaws extending from said distal end, opening and closing means for opening and closing the first and second forceps jaws relative to one another,
first electrical means for applying a first electric voltage across the first 25 and second forceps jaws,
an electric power application means extending from said distal end and arranged for being moved through a tissue portion held between the first and second forceps jaws, and
second electrical means for applying a second electric voltage to the 30 electric power application means relative to the first and/or the second forceps jaws.

Preferably, the first electric voltage is substantially equal to the second electric voltage.

35 The currently preferred embodiment of the device according to the invention further comprises a handle fixed to said proximal end of the

tubular member, said handle advantageously comprising forceps activating means for manually activating the opening and closing means, spring load adjusting means for manually adjusting the spring load of the spring loading means, incision activating means for manually activating the movement of the electric power application means through the tissue portion, and switching means for activating the first and second electrical means for applying said first and second electric voltages.

So as to render the device according to the invention as practical as possible for the surgeon and avoid any risk of erroneous operation thereof, in the currently preferred embodiment of the device, the switching means are adapted to cooperate with the incision activating means such that the first electric voltage is applied in the deactivated condition of said incision activating means while the second electric voltage is applied in the activated condition of said incision activating means. Hereby the coagulating power is automatically succeeded by the incision power when the incision activating means are activated.

In the currently preferred embodiment of the device according to the invention the electric power application means comprise a plate member having a blunt leading edge, and the plate member except the leading edge portion is electrically insulated from the surroundings such that electric power only may be supplied to the tissue portion through said leading edge portion exclusively.

In an alternative embodiment of the device according to the invention, the electric power application means may advantageously comprise a wire member arranged for being moved through the tissue portion and for supplying electric power to the tissue portion.

The invention further relates to an electrosurgical device for coagulating and for making incisions in or severing tissue such as for instance blood vessels, said device comprising:
at least one immobilizing means for immobilizing a tissue portion to be coagulated and incised,
first electrical means for applying electric power to the tissue portion immobilized by the immobilizing means for coagulating at least part of

5 said tissue portion,
at least one incision means for making incisions in at least part of said tissue portion,
the immobilizing means comprising adjustable spring loading means for applying an adjustable spring load for immobilizing the tissue portion.

10 Preferably, the spring load is manually adjustable depending on the characteristics of the tissue portion to be immobilized by the immobilizing means.

15 10 In the currently preferred embodiment of the device according to the invention, the immobilizing means comprise first and second moveable forceps jaws and moving means for opening and closing the first and second jaws relative to one another for holding the tissue portion there-between and the moving means comprise adjustable spring loading means for applying an adjustable spring load for closing the first and second jaws relative to one another.

20 20 The invention furthermore relates to a method of severing blood vessels, the method comprising the following steps:
15 applying a first electric power to a portion of the blood vessel adjacent the intended severing location for coagulating the blood and tissue in said region, and
25 applying a second electric power to said region at said severing location for severing the blood vessel.

30 30 Preferably, said portion of the blood vessel is compressed prior to and/or during the application of the first electric power, the degree of compression being such the blood and tissue coagulates to form a permanent coagulation clot in the blood vessel adjacent said severing location for allowing severing of the blood vessel without bleeding.

35 35 Advantageously, the first and/or the second electrical power is constituted by an electric current signal, an electric voltage signal or a combination thereof, and the signal is a DC or AC signal such as a LF, an HF or an RF signal for instance a VHF, a UHF or a microwave signal.

In the currently preferred embodiment of the method according to the invention, the first and second electric powers are obtained by means of substantially identical electric current or voltage signals.

5 Although any suitable values of the electric powers and any suitable signal frequency may be utilized for various purposes, in the currently preferred embodiment of the method according to the invention, the first and/or second electric powers are delivered by a 60 watt 500 kHz generator.

10 Finally, the invention furthermore relates to a method of coagulating and for making incisions in or severing tissue such as for instance blood vessels, the method comprising the following steps:

15 providing at least one immobilizing means for immobilizing a tissue portion to be coagulated and incised,

providing first electrical means for applying a first electric power to the tissue portion immobilized by the immobilizing means for coagulating at least part of said tissue portion,

20 providing at least one electric power application means for applying a second electric power to at least part of said tissue portion,

immobilizing said tissue portion by applying said immobilizing means to the tissue portion,

applying the electric power to the tissue portion for coagulating at least part of the tissue portion, and

25 applying the second electric power to at least part of said tissue portion for at least assisting in performing an incision in or severing the tissue portion.

30 Advantageously, the first and/or the second electrical power is constituted by an electric current signal, an electric voltage signal or a combination thereof, and the signal is a DC or AC signal such as a LF, an HF or an RF signal for instance a VHF, a UHF or a microwave signal.

35 In the currently preferred embodiment of the method according to the invention, the first and second electric powers are obtained by means of substantially identical electric current or voltage signals.

Although any suitable values of the electric powers and any suitable signal frequency may be utilized for various purposes, in the currently preferred embodiment of the method according to the invention, particularly when being utilized for severing blood vessels, the first and/or second electric powers are delivered by a 60 Watt 500 kHz generator.

5 In the following a device according to the invention is described, solely by way of example, with reference to the accompanying drawings where:

10 Fig. 1 is a schematic perspective elevational view of a preferred embodiment of a device according to the invention,

15 Fig. 2 is a schematic lateral partly cut-away view of the device in Fig. 1 shown in reduced scale,

15 Fig. 3 is a schematic partly sectional perspective view of the device in Fig. 1,

20 Figs. 4a-c are partial diagrammatic illustrative views of three stages in the operation of the device in Fig. 1,

25 Figs. 5-7 are partial diagrammatic illustrative views illustrating the operation of the device in Fig. 1 when utilized for severing a blood vessel,

30 Fig. 8 is a diagrammatic view of one embodiment of an electric power application means according to the invention shown in increased scale, and

30 Fig. 9 is a diagrammatic view of a second embodiment of an electric power application means according to the invention shown in increased scale.

Referring now to Figs 1-3, the currently preferred embodiment of an electrosurgical device according to the invention comprises an elongate rigid tube 1 made from a glass fiber reinforced tubing material, with a 35 vinyl ester resin as the matrix, the material being of the type Polygon II CW produced by the Polygon Company but may be made from any suitable material having sufficient strength and being substantially electrically

non-conductive. At one end, the proximal end, the tube 1 is fixedly attached to a handle 2 provided with a trigger lever 3, a spring load adjustment knob 4 and a severing activating push button 5.

5 Two forceps jaws 6 and 7 protrude from the distal end of the tube 1, the jaws 6 and 7 each being formed by bending a length of steel wire 8 and 9, respectively, so as to form the jaws 6 and 7 and camming portions 10 and 11, respectively, the two end portions of each wire 8 and 9 being embedded in an electrically non-conductive cylinder 12 longitudinally
10 slideably arranged in the lumen of the tube 1. The lengths of wire 8 and 9 are furthermore bent such that a spring force is achieved tending to force the jaws 6 and 7 away from one another, the jaws being forced to abut each other in the de-activated condition of the device shown in Fig. 3 by the cooperation of the distal edge of the tube 1 and the camming portions
15 10 and 11.

The cylinder 12 is fixedly attached to the distal ends of two rigid, electrically conductive rods 13 and 14 that are electrically connected to the wires 8 and 9, respectively, and the rods 13 and 14 are attached at the proximal ends thereof to an electrically non-conductive block 15 longitudinally slideably arranged in guide members 16 arranged on the lateral inner surfaces of the handle 2. The trigger lever 3 is pivotably arranged about a pivot 17 and is provided with a protuberance 18 engaging a recess 15a in the block 15 such that pivoting of the trigger lever 3 around the pivot 17 causes the block 15 to slide to and fro longitudinally in the guide members 16 in the handle 2. Movement of the block 15 in the distal direction causes the cylinder 12 and the wires 8 and 9 to move in the distal direction whereby the forceps jaws 6 and 7 move away from each other because of said spring force in the wires 8 and 9 and the cooperation between the camming portions 10 and 11 with the distal edge of the tube 1.

When the trigger lever 3 is fully depressed the forceps jaws 6 and 7 are in the open position shown in Fig. 5. When the trigger lever 3 is in the de-activated position, the block 15 is at its furthermost proximal position and the forceps jaws abut each other because of the inherent spring force in the wires 8 and 9 and the camming cooperation between the camming portions

10 and 11 and the distal edge of the tube 1. However, the force achieved by this cooperation is relatively weak and not sufficient to clamp and compress a blood vessel as shown in Fig. 6. Therefore an additional spring force is applied to move the forceps jaws 6 and 7 towards one another as 5 explained below.

A coil spring 19 with two arms 19a and 19b is arranged on a pin 20, the 10 end of the arm 19a being pivotably attached to the trigger lever 3 and the end of the arm 19b being pivotably attached to a protuberance 4a of the knob 4, the knob 4 and protuberance 4a being slideably arranged in an arcuate slot 21 in the handle 2. The spring force applied to the trigger lever 3 by the coil spring 19 is thus adjustable by sliding the protuberance in the slot 21. The spring force applied to the trigger lever 3 biasses the 15 block 15 in the proximal direction thereby exerting a relatively large force for moving the forceps jaws 6 and 7 towards one another and for clamping and compressing a blood vessel therebetween. The shape and orientation of the slot 21 relative to the spring 19 and the pin 20 determine the number 20 of possible settings of the spring force exerted by the spring 19. In this embodiment, a maximum spring force and a minimum spring force are obtainable by placing the knob 4 at the left and right end of the slot 21, respectively.

Referring now to Figs. 3 and 4a-c, an elongate plate shaped electric power 25 application electrode or member 22 is slideably arranged in the lumen of the tube 1 such that it may slide longitudinally from a retracted position entirely within the distal portion of the tube 1 as shown in Figs. 3 and 4a-b and an extended position shown in Fig. 4c protruding from the tube 1 and located between the two legs of each forceps jaw 6 and 7. The proximal end of the electrode 22 is fixedly attached to the distal end of a rigid 30 electrically conductive rod 23 extending slideably through a central bore in the cylinder 12 and slideably through a bore in the block 15, the proximal end of the rod 23 being fixedly attached to a plate member 24 attached to the push button 5 arranged longitudinally slidably in an aperture in the handle 2 under the biassing influence of a coil spring 25. The rod 23 is 35 along the length thereof extending in the lumen of the tube 1 surrounded by an electrically insulating material.

By depressing the push button 5 in the distal direction against the biassing force of the coil spring 25, the rod 23 is displaced longitudinally in the distal direction thereby displacing the electrode 22 in the distal direction from the retracted to the extended position thereof while the action of the 5 coil spring 25 will reverse this displacement when pressure is not applied to the push button 5 thereby retracting the electrode 22 into the distal end of the tube 1.

Referring now to Figs. 8 and 9, two alternative embodiments of the 10 electric power application electrode or member 22 are illustrated. In Fig. 9 the electrode comprises an electrically insulated proximal body 22a and an electrically uninsulated distal wire 22b electrically connected to the rod 23. In Fig. 8 the electrode comprises a plate member electrically connected to the rod 23 and having an electrically insulated body 22c having an 15 electrically uninsulated distal blunt edge 22d. Neither the wire 22b nor the blunt edge 22d are able to perform any mechanical cutting function on any tissue when the electrode 22 is displaced from the retracted proximal position to the extended distal position thereof. The insulating material utilized for the electrical insulation of the body region of the electrode is 20 black polyvinylidene fluoride of the type KBM-100 produced by Plastronics US, Inc. of Alpharetta, GA 30201.

Referring now to Fig. 3, a power cable 26 leading from a 60 Watt 500 25 kHz generator (not shown) is connected to an electrical switch 27 that will be described more in detail in the following. An electrical lead 28 electrically interconnects a terminal 28a of the switch 27 and the rod 23 and thereby the electrode 22. Electrical leads 29 and 30 electrically interconnect terminals 29a and 30a, respectively, of the switch 27 with the rods 13 and 14, respectively, and thereby with the wires 8 and 9, respectively. 30

Referring now to Figs. 6 and 7 an electrical diagram of the switch 27 is shown illustrating that in the situation shown in Fig. 6 wherein a blood vessel V is clamped between the forceps jaws 6 and 7 voltage is applied across the forceps jaws as the terminal 29 and 30 are electrically connected 35 to the power cable 26 and thereby to the generator whereby a coagulation of the tissue and blood between the jaws takes place. In the situation shown in Fig. 7 a voltage is applied across the uninsulated wire 22b or the

uninsulated tip region 22d of the electrode 22 in an extended position of said electrode 22 and both the forceps jaws 6 and 7 thereby giving rise to a thermal influence of the tissue adjacent the wire 22b or the tip region 22d and particularly the edge 22e.

5

The switching function of the switch 27 between the coagulating position of Fig. 6 and the severing position of Fig. 7 is achieved by means of two spring tongues 31 and 32 arranged on the top surface of the switch 27, the spring tongues being depressed by the plate 24 when the push button 5 is 10 displaced in the distal direction.

15

In use, the surgeon operating the device first decides which spring load to set by means of the knob 4 depending on the character of the tissue portion, for instance the blood vessel to be severed. Thereafter the surgeon depresses the trigger lever 3 so as to separate the forceps jaws 6, 7 relative to one another, Fig. 5. The forceps jaws are then placed around the vessel and the trigger lever 3 is released so that the forceps jaws are retracted slightly and are moved towards one another by the action of the spring 19, Fig. 6 and the cooperation between the camming portions 10 and 11l and 20 the distal end of the tube 1. The voltage across the forceps jaws coagulates the tissue and any blood in the vessel therebetween. Thereafter the surgeon gradually depresses the push button 5 thereby extending the electrode 22 and simultaneously and automatically switching the voltage from coagulation mode across the forceps jaws 6 and 7 to the severing mode 25 across the electrode 22 and both jaws 6, 7, Fig. 7.

30

As no mechanical cutting effect is involved, the toughness of the tissue to be severed has no effect on the force to be exerted on the push button 5, and the severing action is smooth and gradual with no snap effect as with known mechanical cutting instruments in the known devices.

35

The person skilled in the art will readily understand that many of the features described above in relation to the embodiment shown in the drawings may be varied and modified without departing from the scope of the invention as defined in the appended patent claims.

Thus, the electrode may have any suitable shape such as pointed,

bifurcated, spherical, cylindrical and so on as long as sufficient thermal influence can be caused by the electrical power applied to the electrode.

As mentioned above, the electrode may, for certain applications, have a
5 mechanically cutting edge so as to be able to utilize mechanical cutting in addition to the thermal influence cutting. However, the security of the device will thereby be impaired as the risk of cutting through not sufficiently coagulated tissue or blood vessels will be higher as discussed above.

10

The diameter of the tube 1 may be any suitable value such as 5 mm or 10 mm and the materials chosen for the various components may be modified as long as the requirements of biological non-toxicity and sterility are met.

15

The spring loading of the immobilizing means such as the described forceps jaws or any other suitable immobilizing means may be achieved by other means than the described coil spring, for instance a cylinder-piston mechanism with adjustable pressure.

20

The tube 2 may be replaced by any other suitable means for locating the immobilizing means and electrical power application means adjacent the tissue to be coagulated and incised, for instance two or three parallel or concentric tubes, one or two for the immobilizing means and one for the electric power application means.

25

EXAMPLE

DIMENSIONS

30

Total length of device parallel to axis of tube 1: 465 mm.

Handle size: 75x145x20mm

Tube 1 or cannula: 300 mm

Cannula diameter: 10 mm

Forceps size: 1.5 mm wire, U-form 4.5x25mm (closed)

35

Plate electrode: 22x6.2x0.28mm

Cable: 3 metre with 2x4 male connector

COMPONENTS

Handle + push button + trigger lever: Material: ABS

Cannula: Material: Vinyl ester resin with glass fibre reinforcement

5 Forceps: Material: Stainless steel spring wire (AISI 302)

Plate electrode: Material: Stainless steel covered by KYNAR KBM 100

Connector: Material: Nickel plated brass with plastic housing

Cable: Material: CU with PVC insulation

Sterilization of entire device by electron irradiation.

10

For contemplated smaller diameters of the tube 1, for instance 5 mm, the rigidity achievable with glass fibre reinforced vinyl ester resin matrix may not be sufficient and therefore it is contemplated to make the tube 1 of stainless steel. In such case the regions of the forceps jaw wires 8 and 9

15

extending from the cylinder 12 to the distal end of the camming portions 10 and 11, i.e. the regions of the wires being able to come into contact with the distal edge of the tube 1, are contemplated being electrically insulated by means of KYNAR KBM 100 to avoid electrical connection between the forceps jaws and the tube 1.

20

TEST OF CUTTING FUNCTION

Objective

25

To examine the possible advantage of applying an active electrode to perform the cutting function compared to a sharp blade with mechanical cutting function.

30

The objective is based on the statements from surgeons using a similar device where they claimed that the mechanical cutting blade became blunt.

Test

Three tests were conducted on a piece of meat:

35

1. **Transection with a mechanically cutting blade:** After coagulating the meat with the forceps, the sharp cutting blade was advanced

through the meat. This procedure was repeated several times (on fresh meat zones) while monitoring/sensing the blade's cutting ability.

5 Conclusion: After having repeated the procedure 6 times there was a clear difference in the smoothness of the cutting function. The blade seemed to push the meat out of the forceps and more pressure had to be applied to perform the transection.

10 2. **Transection with a non-active blunt electrode (without applying electric power):** After coagulating the meat with the forceps, the blunt electrode was advanced to perform transection.

15 Conclusion: The blunt electrode could not cut its way through the meat, but instead pushed it out of the forceps. The electrode could only make a very rough and uncontrolled preliminary cut when pressed forward with a very strong force.

20 3. **Transection with an active blunt electrode:** After coagulating the meat with the forceps, the active electrode was advanced to perform transection. The active electrode performed the cutting very smoothly, and the resistance to the meat was clearly minimized, hence the self cutting effect of the electric power or electrosurgical energy.

25 Conclusion: This procedure was performed continuously for 25 times and the electrode performed the cutting smoothly and without damage to the meat. There seemed no reason why it should not be able to continue cutting the meat. Only the electrode had to be cleaned once due to meat adhering on the edge.

30 **Final Conclusion**

35 From the above tests, it was concluded that the active electrode gave a significantly better long term performance and an incision which was fully acceptable compared to a mechanically cutting blade. In fact, the active electrode seemed to perform a superficial coagulation of the incision, thus securing a complete coagulation of blood vessels.

PATENT CLAIMS

1. An electrosurgical device for coagulating and for making incisions in or
5 severing tissue such as for instance blood vessels, said device comprising:
 - at least one immobilizing means for immobilizing a tissue portion to be coagulated and incised,
- 10 - first electrical means for applying a first electric power to the tissue portion immobilized by the immobilizing means for coagulating at least part of said tissue portion and
 - at least one electric power application means for applying a second electric power to at least part of said tissue portion for making incisions in said tissue portion.
- 15 2. A device according to claim 1 wherein the electric power application means is configured such, for instance being blunt, that the incision or severing is substantially exclusively achieved by means of said second electric power.
- 20 3. A device according to claim 1 or 2 wherein the first and/or the second electrical power is constituted by an electric current signal, an electric voltage signal or a combination thereof.
- 25 4. A device according to claim 3 wherein the signal is a DC or AC signal such as a LF, an HF or an RF signal for instance a VHF, a UHF or a microwave signal.
- 30 5. A device according to claim 1 or 2 wherein the first and second electric powers are obtained by means of substantially identical electric current or voltage signals.
- 35 6. A device according to any of the claims 1-5 wherein the immobilizing means comprise first and second moveable forceps jaws and moving means for opening and closing the first and second jaws relative to one

another for holding and/or clamping the tissue portion therebetween.

7. A device according to claim 6 wherein the moving means comprise
adjustable spring loading means for applying a specific or an adjustable
5 spring load for closing the first and second jaws relative to one another.

8. A device according to claim 7 wherein the spring load is manually
10 adjustable depending on the characteristics of the tissue portion to be held
between said jaws.

10 9. A device according to any of the preceding claims and furthermore
comprising electrical switching means for applying the first and second
electric powers independently of one another and preferably sequentially.

15 10. A device according to any of the preceding claims and comprising:

- an elongated tubular member having a proximal and a distal end and a
lumen extending therethrough,
20 - first and second moveable forceps jaws extending from said distal end,
- opening and closing means for opening and closing the first and second
forceps jaws relative to one another,
25 - first electrical means for applying a first electric voltage across the first
and second forceps jaws,
- an electric power application means extending from said distal end and
arranged for being moved through a tissue portion held between the first
30 and second forceps jaws, and

- second electrical means for applying a second electric voltage to the
electric power application means relative to the first and/or the second
forceps jaws.

35 11. A device according to claim 10 wherein the first electric voltage is
substantially equal to the second electric voltage.

12. A device according to claim 10 or 11 and further comprising a handle fixed to said proximal end of the tubular member.
- 5 13. A device according to claim 12 wherein the handle comprises forceps activating means for manually activating the opening and closing means.
- 10 14. A device according to claim 12 or 13 wherein the handle comprises spring load adjusting means for manually adjusting the spring load of the spring loading means.
- 15 15. A device according to any of the claims 12-14 wherein the handle comprises incision activating means for manually activating the movement of the electric power application means through the tissue portion.
16. A device according to any of the claims 12-15 wherein the handle comprises switching means for activating the first and second electrical means for applying said first and second electric voltages.
- 20 17. A device according to claim 16 wherein the switching means are adapted to cooperate with the incision activating means such that the first electric voltage is applied in the deactivated condition of said incision activating means while the second electric voltage is applied in the activated condition of said incision activating means.
- 25 18. A device according to any of the preceding claims wherein the electric power application means comprise a plate member having a blunt leading edge.
- 30 19. A device according to claim 18 wherein the plate member except the leading edge portion is electrically insulated from the surroundings such that electric power only may be supplied to the tissue portion through said leading edge portion.
- 35 20. A device according to any of the claims 1-14 wherein the electric power application means comprise a wire member arranged for being moved through the tissue portion and for supplying electric power to the

tissue portion.

21. An electrosurgical device for coagulating and for making incisions in or severing tissue such as for instance blood vessels, said device

5 comprising

- at least one immobilizing means for immobilizing a tissue portion to be coagulated and incised,

10 - first electrical means for applying electric power to the tissue portion immobilized by the immobilizing means for coagulating at least part of said tissue portion,

15 - at least one incision means for making incisions in at least part of said tissue portion,

the immobilizing means comprising adjustable spring loading means for applying an adjustable spring load for immobilizing the tissue portion.

20 22. A device according to claim 21 wherein the spring load is manually adjustable depending on the characteristics of the tissue portion to be immobilized by the immobilizing means.

25 23. A device according to claim 21 or 22 wherein the immobilizing means comprise first and second moveable forceps jaws and moving means for opening and closing the first and second jaws relative to one another for holding the tissue portion therebetween.

30 24. A device according to claim 23 wherein the moving means comprise adjustable spring loading means for applying an adjustable spring load for closing the first and second jaws relative to one another.

35 25. A method of severing blood vessels, the method comprising the following steps:

- applying a first electric power to a portion of the blood vessel adjacent the intended severing location for coagulating the blood and tissue in said

region, and

- applying a second electric power to said region at said severing location for severing the blood vessel.

5

26. A method according to claim 25 wherein said portion of the blood vessel is compressed prior to and/or during the application of the first electric power, the degree of compression being such that the flow of blood through the blood vessel is such that the blood and tissue for 10 coagulates to form a permanent coagulation clot in the blood vessel adjacent said severing location for allowing severing of the blood vessel without bleeding.

15

27. A method according to claim 25 or 26 wherein the first and/or the second electrical power is constituted by an electric current signal, an electric voltage signal or a combination thereof.

20

28. A method according to claim 27 wherein the signal is a DC or AC signal such as a LF, an HF or an RF signal for instance a VHF, a UHF or a microwave signal.

25

29. A method according to claim 27 or 28 wherein the first and second electric powers are obtained by means of substantially identical electric current or voltage signals.

30

30. A method according to any of the claims 25-29 wherein the first and/or second electric powers are delivered by a 60 Watt 500 kHz generator.

35

31. A method of coagulating and for making incisions in or severing tissue such as for instance blood vessels, the method comprising the following steps:

35

- providing at least one immobilizing means for immobilizing a tissue portion to be coagulated and incised,

35

- providing first electrical means for applying a first electric power to the

tissue portion immobilized by the immobilizing means for coagulating at least part of said tissue portion,

- 5 - providing at least one electric power application means for applying a second electric power to at least part of said tissue portion,
- 10 -immobilizing said tissue portion by applying said immobilizing means to the tissue portion,
- 15 - applying the electric power to the tissue portion for coagulating at least part of the tissue portion, and
 - 20 - applying the second electric power to at least part of said tissue portion for at least assisting in performing an incision in or severing the tissue portion.
- 25 32. A method according to claim 31 wherein the first and/or the second electrical power is constituted by an electric current signal, an electric voltage signal or a combination thereof.
- 30 33. A method according to claim 32 wherein the signal is a DC or AC signal such as a LF, an HF or an RF signal for instance a VHF, a UHF or a microwave signal.
- 35. A method according to any of the claims 31-34 wherein the first and/or second electric powers are delivered by a 60 Watt 500 kHz generator.

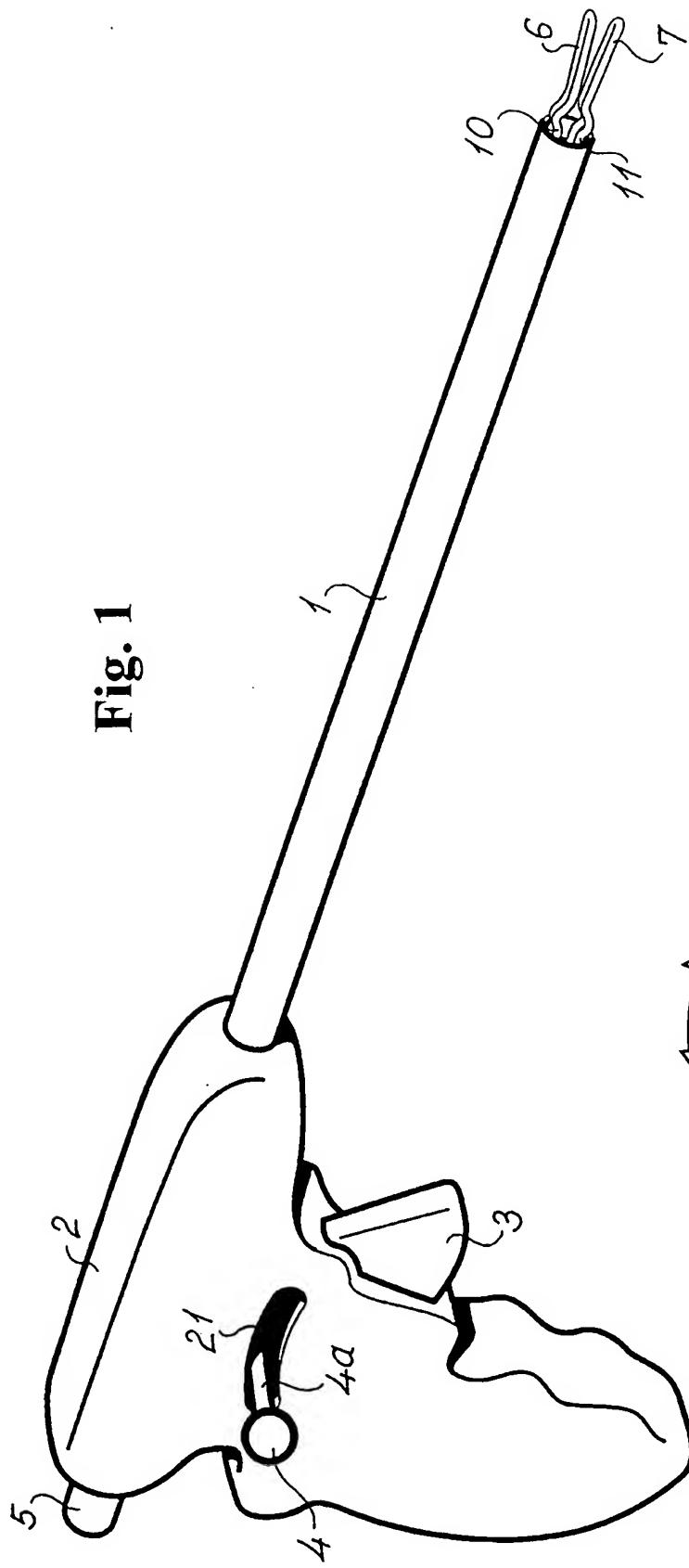


Fig. 1

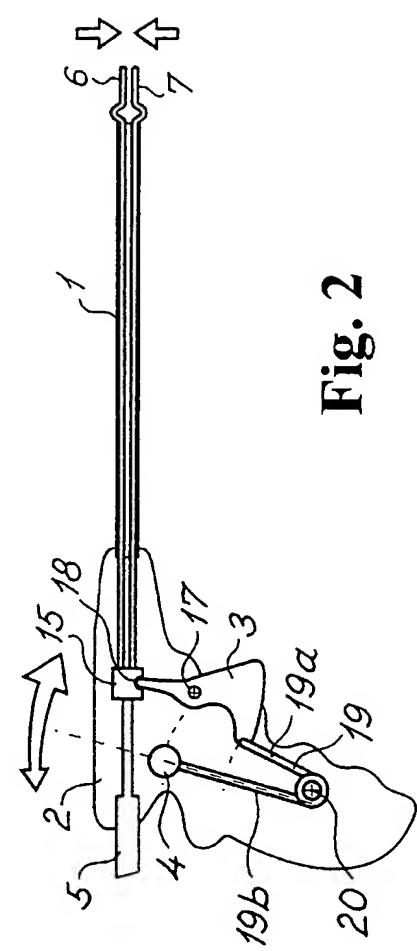
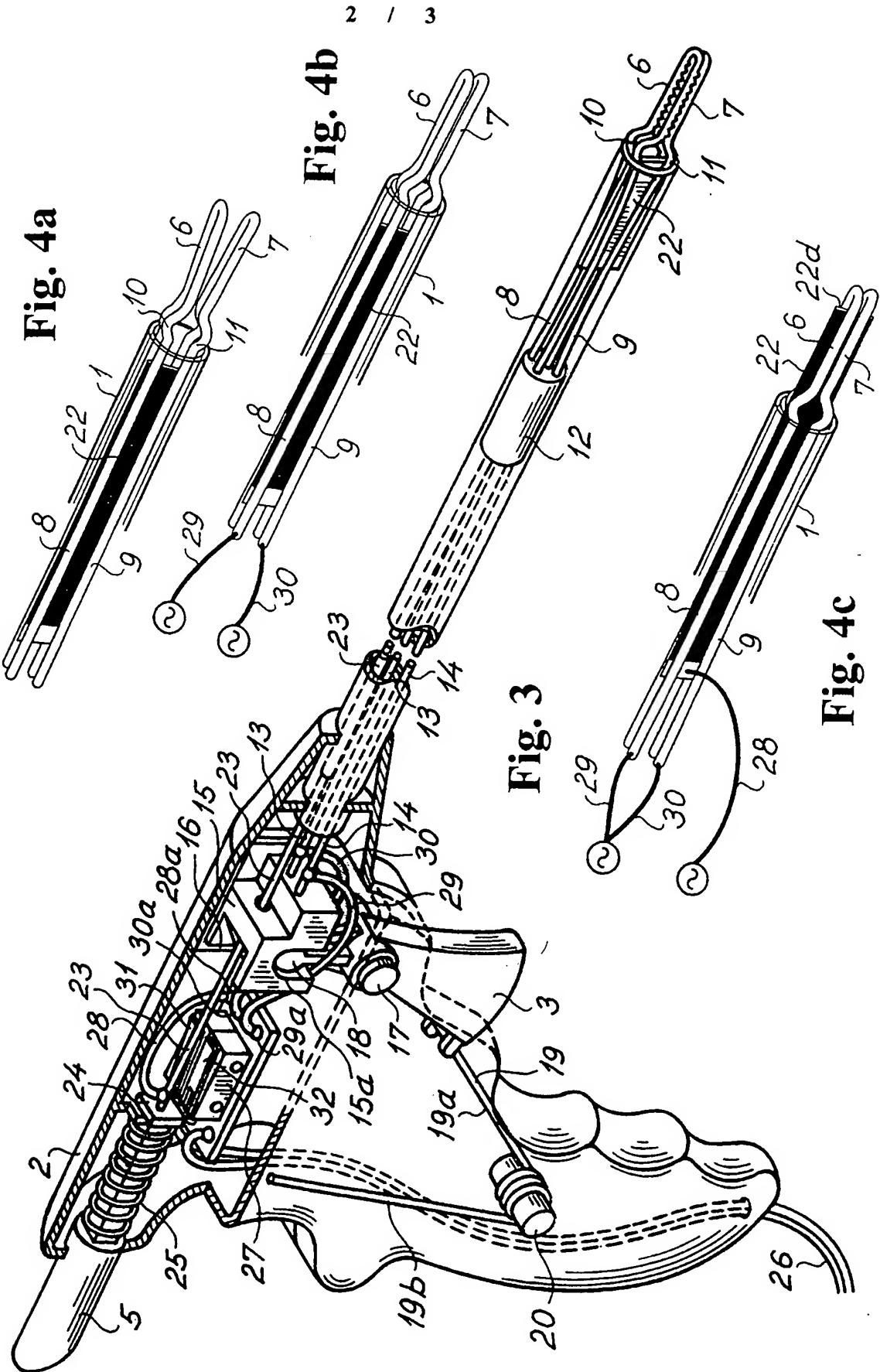


Fig. 2



3 / 3

Fig. 5

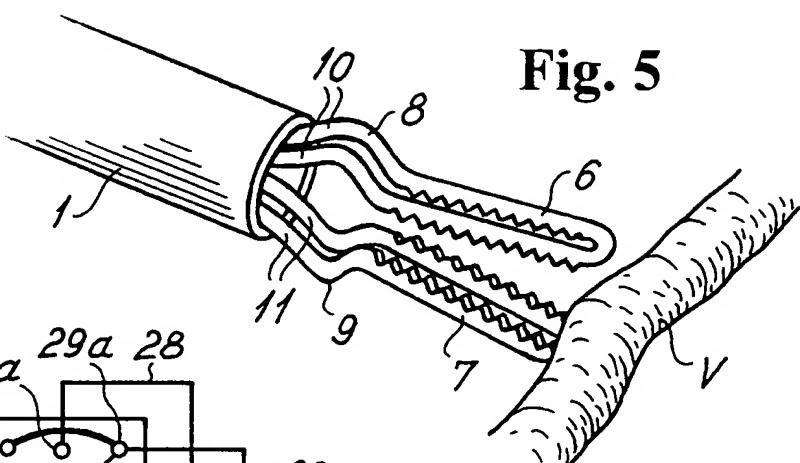


Fig. 6

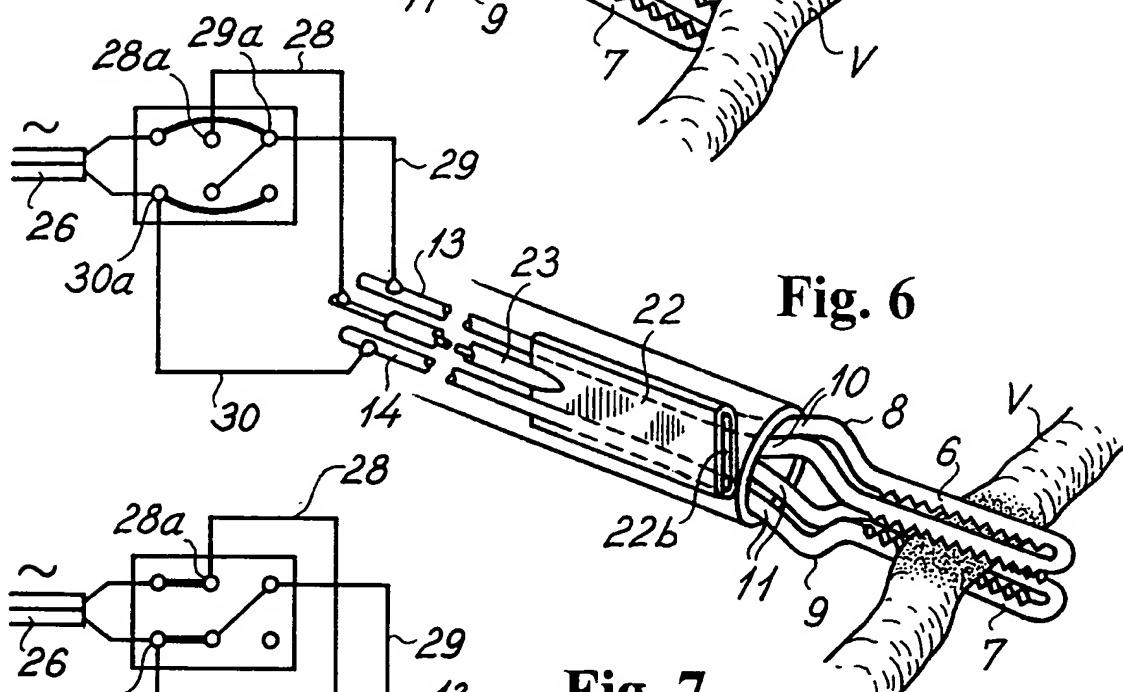


Fig. 7

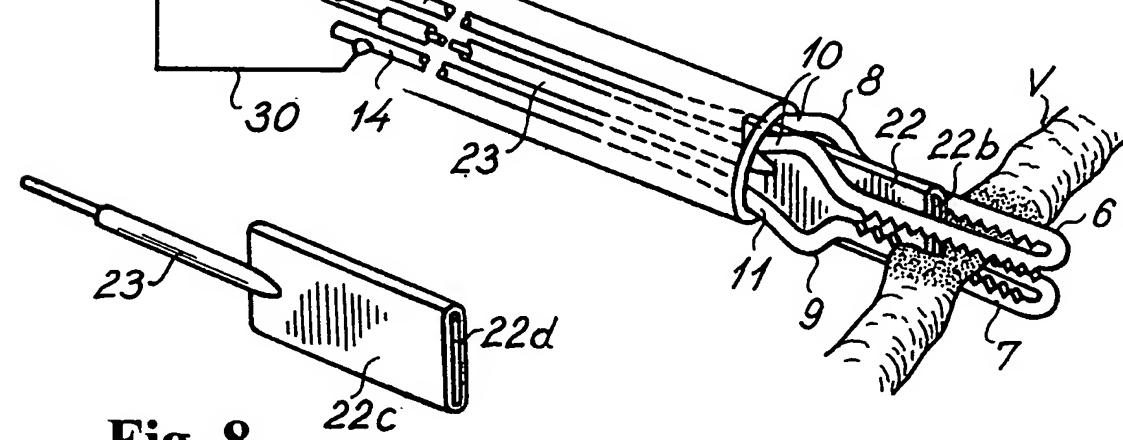


Fig. 8

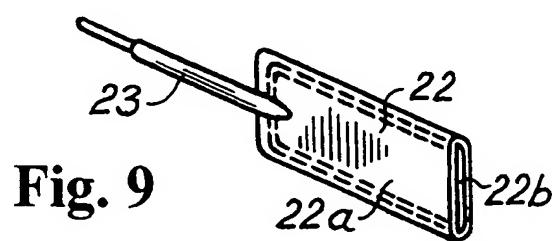


Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 98/00276

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5403312 A (DAVID C. YATES ET AL), 4 April 1995 (04.04.95), column 5, line 46 - line 49; column 6, line 24 - line 38 --	1
A	US 5445638 A (MARK A. RYDELL ET AL), 29 August 1995 (29.08.95), column 4, line 55 - column 5, line 2, figure 3 -- -----	1

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

18 February 1999

Date of mailing of the international search report

25 -02- 1999

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. + 46 8 666 02 86

Authorized officer

Anette Hall
Telephone No. + 46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK98/00276

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 25–35
because they relate to subject matter not required to be searched by this Authority, namely:
A method of treatment of the human or animal body by surgery (Article 17(2) (a) (i) and Rule 39.1(iv)).
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/02/99

International application No.

PCT/DK 98/00276

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5403312 A	04/04/95	AU 687405 B	26/02/98
		AU 6862294 A	02/02/95
		CA 2128450 A,C	23/01/95
		EP 0640317 A	01/03/95
		GR 94100336 A	22/05/96
		JP 7171163 A	11/07/95
		US 5558671 A	24/09/96
		US 5688270 A	18/11/97
		US 5693051 A	02/12/97
		US 5709680 A	20/01/98
		US 5807393 A	15/09/98
		US 5810811 A	22/09/98
		US 5817093 A	06/10/98
		US 5833690 A	10/11/98
-----	-----	-----	-----
US 5445638 A	29/08/95	NONE	-----
-----	-----	-----	-----

THIS PAGE BLANK (USPTO)